

PATENT COOPERATION TREATY

PCT

REC'D 13 DEC 2004

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

PCT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 4700-597PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/US 03/20579	International filing date (day/month/year) 27.06.2003	Priority date (day/month/year) 01.10.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/48		
Applicant BANNER PHARMACAPS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

I	<input checked="" type="checkbox"/>	Basis of the opinion
II	<input type="checkbox"/>	Priority
III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/>	Lack of unity of invention
V	<input checked="" type="checkbox"/>	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/>	Certain documents cited
VII	<input type="checkbox"/>	Certain defects in the international application
VIII	<input type="checkbox"/>	Certain observations on the international application

Date of submission of the demand 22.04.2004	Date of completion of this report 10.12.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Luangkhot, N Telephone No. +49 89 2399-7857 

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EXAMINATION REPORT**

International application No. **PCT/US 03/20579**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, Pages

1-17 as originally filed

Claims, Numbers

1-23 filed with telefax on 04.10.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-23
Inventive step (IS)	Yes: Claims	
	No: Claims	1-23
Industrial applicability (IA)	Yes: Claims	1-23
	No: Claims	

2. Citations and explanations

see separate sheet

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Re Item I

Basis of opinion

- 1) New set of claims 1-23 is allowable according to Article 34(2)(b) PCT because a support was found in the description and no subject-matter which extends beyond the content of the application as filed was introduced.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 2) The documents cited in the International Search Report (ISR) were numbered respectively from D1-D7; this numbering results from the citation order in the ISR and will be used for the procedure. **The cited passages of each document in the ISR will be considered.**

3) Novelty and inventive step according to Art. 33(2) and 33(3) PCT

- ~~3a) The subject-matter of claims 1-23 is not novel and/or not inventive in view of prior art D1-D5 (see whole documents) because these latter describes or suggests a gel mass composition comprising:~~

- a/ a WSP (water-soluble polymer) such as gelatine
- b/ an AIP (acid insoluble polymer) such as a conventional enteric polymer
- c/ an aqueous solvent such as water or an alkaline or a hydroalcoholic solution
- d/ optionally a plasticizer
- e/ eventually a coloring agent,

wherein the ratio b:a and the ratio d:a seem to fall within the range of present claims 17 and 18 (see D1: examples 2,5,6 and 9; D2: examples 1b and 2b; D3: example 3; D4: claims 3,4,8,10 and example 7; D5: Table 7).

In particular D4 and D5 teach that the water content of the material should lie between 5-25%, and more preferably around 10%.

- 3b) Even if the applicant is able to overcome the novelty objections for claims 5,6 (directed to the use of a carbohydrate such as HPMC), claims 14-16,20 (directed to the moisture content of the shell), and claims 22 and 23 (directed to the thickness of the film), the subject-matter of the said claims seems not to involve the necessary

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inventive step because it seems that the use of HPMC, the setting of the moisture content or the thickness of the film **are features which appear not to be essential to the invention**. They appear indeed as obvious or non inventive alternatives that the skilled man in the art would perform in order to distinguish from prior art.

The applicant should provide comparative tests showing that these features are essential to the invention and that they are not implicit nor inherent in the compositions disclosed in the prior art.

Furthermore the applicant should show a surprising effect, wherein **said surprising effect is specifically attributed to the said features**.

As long as these data are missing, the said features are considered as an obvious alternative that the skilled man in the art will introduce in order to distinguish from prior art and inventive step cannot be acknowledged in view of D1-D5 each taken alone, or in combination thereof.

For the regional phase:

- 4) Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application.
- 5) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D5 is not mentioned in the description, nor are these documents identified therein.
- 6) In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT). Preferably these indications should be submitted in **handwritten form** on a copy of the relevant parts of the application as filed.